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Attorney's Docket No.: 17072-002001

Client's Ref. No.: 0271

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Applicant : Robert Thomas Hudak  
Serial No. : 09/915,494  
Filed : July 25, 2001

Art Unit : 1641  
Examiner : Gary W. Counts

Title : Specimen Collection Container

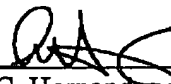
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Commissioner for Patents  
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Attached to this facsimile communication cover sheet is **NOTICE OF APPEAL, PRE-APPEAL BRIEF REQUEST FOR REVIEW, and APPLICANT'S REMARKS FOR PRE-APPEAL BRIEF CONFERENCE**, faxed this 2<sup>nd</sup> day of February, 2006, to the United States Patent and Trademark Office.

Respectfully submitted,

Date: February 2, 2006

  
\_\_\_\_\_  
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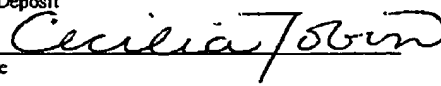
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PTO/SB/33 (07-05)  
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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number: 17072-002001 / 0271
I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below, to 571-273-8300.  February 2, 2006 Date of Deposit  Signature Cecilia Tobin Typed or Printed Name of Person Signing Certificate	Application Number 09/915,494	Filed July 25, 2001
	First Named Inventor Robert Thomas Hudak	
	Art Unit 1641	Examiner Gary W. Counts
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a Notice of Appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record <u>41,832</u> (Reg. No.)</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p> <p><input type="checkbox"/> Total of no. forms are submitted.</p>		

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FEB 02 2006

Attorney's Docket No.: 17072-002001 / 0271

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Robert Thomas Hudak                      Art Unit : 1641  
Serial No. : 09/915,494                                      Examiner : Gary W. Counts  
Filed : July 25, 2001  
Title : SPECIMEN COLLECTION CONTAINER

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**APPLICANT'S REMARKS FOR PRE-APPEAL BRIEF CONFERENCE**

Consideration of the following remarks is respectfully requested with respect to the pre-appeal brief conference for the above-captioned case.

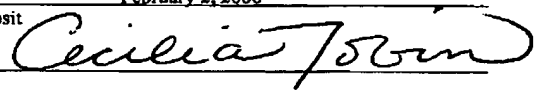
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February 2, 2006

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Cecilia Tobin

Typed or Printed Name of Person Signing Certificate

Applicant : Robert Thomas Hudak  
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Filed : July 25, 2001  
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## **REMARKS**

### **Background**

The present invention involves a specimen collection device. In one embodiment the device has the general form of a cup and is useful for detecting analytes (e.g., illicit drugs) in a urine sample. The device has a chamber for collecting the specimen, a reservoir having a test device for analyzing the sample (e.g., a test card), and a valve positioned in between the chamber and reservoir, which can be activated to move a quantity of sample from the chamber to the reservoir. The valve is designed so that it can be operated only once, and is inoperable after a first actuation.

A problem encountered in detecting analytes in samples is providing assurances that a positive result is genuine, and is not due to contamination of the sample with assay reagents or deliberate tampering with the sample by a device operator. The present invention solves this problem by providing a device having the valve that is operable only a single time. After activation of the valve, the valve is inoperable. Thus, once the valve is activated, it cannot be reversed and sample is unable to travel from the reservoir back to the chamber (nor vice versa). A portion of sample is retained in the chamber, and the operator can be assured that the sample in the chamber is not contaminated by any reagents in the reservoir.

### **Argument**

Presently, the Examiner maintains that claims 74-75, 79, 85-92 and 94-102 are anticipated by Cui (US 6,576,193). The Examiner also maintains that claims 76-78, 80-84 and 93 are obvious over Cui in view of various cited references. The Applicant maintains that claim 74 is clearly not anticipated by Cui, and that the various secondary references cited by the Examiner completely fail to remedy the deficiencies of Cui, and thus that the cited claims are not obvious over the cited combinations of references.

The last limitation of claim 74 recites "the valve being inoperable after a first activation." The Examiner maintains that this limitation can be disregarded because "it is intended use [sic] of the valve and a recitation of the intended use of the claimed invention must result in a

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structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.”<sup>1</sup> The Examiner cites no legal or administrative authority to support this position.<sup>2</sup> Nor does the Examiner specify the presumed intended use indicated by the claim limitation.

The Applicant maintains that the limitation “the valve being inoperable after a first activation” is a genuine limitation of the claim entitled to consideration like any other limitation. The Applicant maintains this recitation is not an “intended use” at all, but is a stated characteristic of the valve. The Applicant has cited case law that clearly establishes that each element contained in a patent claim is deemed material to defining the scope of the claim. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17; 41 USPQ2d 1865 (1997), *on remand*, 114 F.3d 1161; 43 USPQ2d 1152 (Fed. Cir. 1997). (Order per curiam). The Applicant points out that even if the limitation at issue were found to be functional language, case law also establishes that even functional language in a claim cannot be disregarded. *Pac-Tec., Inc. v. Amerace Corp.* 903 F.2d 796; 14 USPQ2d 1871 (Fed. Cir. 1990), *cert denied sub non. Perry v. Amerace Corp.* 502 U.S. 808 (1991).

Properly made rejections under 35 U.S.C 102 require that each and every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001). The reference must teach every aspect of the claimed invention either explicitly or impliedly. MPEP 2131.

The cited limitation must be considered as a genuine characteristic of the valve. Since Cui does not disclose or suggest a valve that is inoperable after a first activation, claim 74 and its dependent claims are not anticipated.

A proper rejection under 35 U.S.C. 103 requires that the cited references, when combined, teach or suggest all the claim limitations. *In re Vaack*, 947 F.2d 488; 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP 2142. None of the cited references teach the limitation of a valve that is inoperable after a first activation, nor has the Examiner stated that any of the references disclose such a limitation. The Examiner has instead stated that the recitation of a

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<sup>1</sup> Office Action mailed 1/12/06, p. 3.

<sup>2</sup> *Id* at p 8, line 16.

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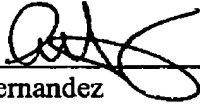
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"valve being inoperable after a first actuation" has no patentable weight for the (improper) reasons stated above. For reasons explained above, this recitation is a genuine limitation of the claim that must be considered. Therefore, no prima facie case of obviousness has been established and no proper rejection under Section 103 has been properly made.

### Conclusion

Applicant respectfully submits that the pending claims are now in condition for allowance and respectfully requests the same. If the Examiner(s) has/have any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: February 2, 2006  
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